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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,248	09/17/2001	Leo Martis	DI-4641 CONT	8992

29200 7590 11/19/2003

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ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 11/19/2003

18

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 18

Application Number: 09/955,248
Filing Date: September 17, 2001
Appellant(s): MARTIS ET AL.

Thomas C. Basso
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 11, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-16 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together ***and*** reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Schambye et al. 'The Cytotoxicity of Continuous Ambulatory Peritoneal Dialysis Solutions with Different Bicarbonate/Lactate Ratios" Peritoneal Dialysis International, vol 13, supplement 2 (October 1992), pp. S116-S118

4,663,166	VEECH	5-1987
5,296,242	ZANDER	3-1994
6,020,007	VEECH	2-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

Schambye et al. disclose continuous ambulatory peritoneal dialysis (CAPD) solutions having bicarbonate concentrations ranging from 10-27 mM, lactate concentrations ranging from 20.0-6.7 mM (see abstract on page S116). The most advantageous CAPD solution has a bicarbonate concentration of approximately 20 mM, a lactate concentration of 12.5 mM, and a pH of approximately 7.2 (see page S116, abstract and page S118). Since, Schambye et al. disclose a CAPD solution which has the claimed bicarbonate and weak acid concentrations then the CAPD solution of Schambye et al. inherently exhibit the claimed CO_2 partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO_2 partial pressure (see Zander at column 3, lines 11-16, wherein it is

taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO_2 partial pressure).

The burden shifts to the Applicants to prove that the CAPD solution of Schambye et al. do not necessarily or inherently possess the characteristics of their claimed peritoneal dialysis solution (see In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) and In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

3. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242).

Veech discloses preferred peritoneal dialysis solutions comprising osmotically active substances such as glucose (dextrose, 83-237 mmole/L), sodium (130 to 145 mmole/L), chloride (93 to 102 mmole/L), calcium (1 to 1.5 mmole/L), magnesium (0.3 to 1 mmole/L), bicarbonate (25 to 30 mmole/L), lactate-/plus pyruvate- (2 to 12) and carbon dioxide (0 to 2 mmole/L), see column 41, table VIII and column 37, line 41.

Veech discloses a peritoneal dialysis solution, which has the claimed bicarbonate and weak acid concentrations. Therefore, the peritoneal dialysis solution of Veech inherently exhibits the claimed CO_2 partial pressure (see In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986), since it is the bicarbonate and weak acid that determine the CO_2 partial pressure (see Zander at column 3, lines 11-16, wherein it is taught that the reaction between the bicarbonate and metabolizable organic acid produces the CO_2 partial pressure).

The burden shifts to the Applicants to prove that the peritoneal dialysis solution of Veech does not necessarily or inherently possess the characteristics of their claimed

peritoneal dialysis solution (see In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) and In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242).

Schambye et al. disclose a peritoneal dialysis solution as described above. Schambye et al differ from the instant invention in that Schambye et al. do not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the

physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Schambye et al. in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

7. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242).

Veech discloses peritoneal dialysis solutions as described above. The peritoneal solutions disclosed in Veech tend to maintain a normal equivalent ratio of sodium to chloride, tend to maintain normal plasma and cellular pH and tend to maintain normal cofactor ratios (see column 41, lines 9-14). Thus, upon its use the peritoneal dialysis solution of Veech would inherently correct metabolic acidosis in a dialysis patient suffering from or likely to suffer from metabolic acidosis.

Veech differs from the instant invention in that Veech does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

Veech further differs from claim 15, in that Veech teaches utilizing lactate as the weak acid, whereas claim 15 requires that the solution does not contain lactate.

Zander teaches that in peritoneal dialysis solutions the metabolizable acids can be selected from pyruvic, lactic, oxalic, fumaric, acetic, malic, maleic, malonic and succinic acids. Thus, these acids are taught to be interchangeable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the lactic acid of Veech with any of the metabolizable acids taught by Zander , since Zander implicitly teaches that these acids are equivalent for their use in the peritoneal dialysis art and the selection of any of these known equivalents as the weak acid in Veech would be within the level of ordinary skill in the art.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 6,020,007) in view of Zander (US 5,296,242).

Veech teaches a solution, which can be used to correct acidosis, for dialysis and/or fluid, electrolyte or nutrient replacement (see column 7, lines 34-40). In particular the type C solutions are suitable for use in peritoneal dialysis (see column 8, lines 36-38). The components of the solution are listed in Table II in column 9. The broadest range amount of each component is given in Table II. However, Veech teaches that to be physiologically advantageous it is generally preferred to maintain levels of the components at values, which are approximately physiologic (see column 5, lines 65 to column 6, line 13). The most preferred pH of the solution is about 7.4 (see column 6, lines 44 and 45).

Veech differs from the instant invention in that Veech does not specifically teach that the carbon dioxide partial pressure is approximately the same as the carbon dioxide partial pressure of blood.

Zander discloses sterilizable aqueous solutions that contain the claimed concentrations of the bicarbonate and weak acid, as well as the claimed carbon dioxide partial pressure (see column 2, line 35 to column 6, line 27). Zander discloses

that preliminary research revealed that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure correspond to the physiological blood plasma values (see column 2, lines 35-39). These physiological values are for pH value 7.40+\-0.05, for the bicarbonate concentration 24 mmole/l and for the CO_2 partial pressure 40 mm Hg (see column 2, lines 40-43). Zander discloses that using pH-values (7.40+\-0.05), bicarbonate concentrations (24 mmole/L) and CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

One having ordinary skill in the art at the time the invention was made would have been motivated to modify the bicarbonate and weak acid concentrations of Veech in such a way as to obtain a pCO_2 that is approximately the same as the carbon dioxide partial pressure of blood, since Zander discloses that using CO_2 partial pressures (40 mm Hg) that correspond to physiological blood plasma values would prevent alkalosis or acidosis from occurring.

(11) Response to Argument

The appellants argue that the Patent Office has improperly relied on the combined teachings of Zander with Schambye or Veech I in support of the anticipation rejections because anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. This argument is not persuasive because normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

(A) Prove the primary reference contains an "enabled disclosure; "

(B) Explain the meaning of a term used in the primary reference; or

(C) Show that a characteristic not disclosed in the reference is inherent.

In the instant case multiple references are being used to show that a characteristic not disclosed in the reference is inherent. In particular, Zander is combined with Schambye et al. and Veech I to show that the claimed carbon dioxide partial pressure is inherently taught by Schambye et al. and Veech I.

Appellants argue that nowhere does the cited prior art disclose a peritoneal dialysis solution that combines a specified bicarbonate and weak acid concentration in addition to a specific carbon dioxide partial pressure effective in maintaining an acid-base balance in dialysis patients as required by the claimed invention. The Examiner disagrees. Schambye et al. teach a bicarbonate concentration of between 10-27 mM and a lactate (weak acid) concentration of between 20.8-6.7mM (see column 1 on page S116 and Table 1 on page S117, in particular solution 91c). Veech I teaches a bicarbonate concentration between 0 to 55, preferably 25 to 30 and a lactate plus pyruvate (weak acid) concentration of 0 to 55, preferably 2 to 12 (see Table VIII in column 41). The bicarbonate and weak acid concentrations disclosed by Schambye et al., and Veech I overlap with the claimed bicarbonate and weak acid concentrations. Although the prior art references do not expressly disclose the carbon dioxide partial pressure, it is known from Zander that a reaction occurs between the bicarbonate and weak acid to form carbon dioxide and that this reaction produces the carbon dioxide at a partial pressure of 40 mmHg (see column 3, lines 7-17). Thus, since Schambye et al., and Veech I each teach the claimed bicarbonate and weak acid concentrations and in view of Zander the claimed carbon dioxide partial pressure

is inherently taught, the prior art does indeed disclose a peritoneal dialysis solution that combines a specified bicarbonate and weak acid concentration in addition to a specific carbon dioxide partial pressure. The prior art dialysis solutions are also effective in maintaining an acid-base balance in dialysis patients due to the presence of the metabolizable organic anions (see Zander column 2, lines 64 and 65 and column 3, lines 41-46).

The Appellants argue that the claimed invention is not inherent in view of the cited prior art. The Examiner disagrees. Based on the teachings of Zander carbon dioxide forms, at a partial pressure of 40 mmHg, as a result of a reaction that occurs between the bicarbonate and weak acid (see column 3, lines 11-17 and column 4, lines 36-48). Thus, since the peritoneal dialysis solutions disclosed in Schambye et al. and Veech I contain bicarbonate and a weak acid a reaction between the two will occur and carbon dioxide at a partial pressure of 40 mmHg will necessarily result. For this reason the prior art inherently teaches the claimed invention.

The Appellants argue that Zander teaches away from the peritoneal dialysis solutions as required by the claimed invention because the solutions of Zander lack a weak acid component. The Examiner disagrees. In column 3, lines 62-68, Zander teaches that in addition to bicarbonate the solutions contain a long-term buffer metabolized anion in the desired concentration. Preferred metabolizable acids useable include pyruvic, lactic etc.

The Appellants make statements regarding Zander's teaching of a solution, which combines bicarbonate and acetate. However, the Zander reference is not being used for its teaching of the bicarbonate and weak acid, these limitations are

taught by Schambye et al. and Veech I. Zander is applied as a reference for it's teaching of a reaction between the bicarbonate and weak acid to form carbon dioxide at a partial pressure of 40 mmHg. Nonetheless, Zander does teach using pyruvic and lactic acid (see column 3, lines 62-68).

The Appellants argue that Schambye, Veech I and Veech II do not disclose or suggest the carbon dioxide partial pressure features, let alone the carbon dioxide partial pressure features combined with the additional features. The Examiner disagrees. Each of these prior art references teach using the claimed bicarbonate and weak acid, which according to Zander react to form carbon dioxide at a partial pressure of 40 mmHg. Further Veech I and Veech II both expressly teach that their solutions contain dissolved carbon dioxide (see for example column 13, lines 13-38 of Veech I and column 7, lines 12-14 and claims 2 and 3 of Veech II). Veech I and Veech II do not teach that the carbon dioxide partial pressure (pCO_2) is substantially similar to that found in the patient's blood. However, Zander teaches at column 2, lines 35-39 that dialysis solutions are particularly suitable if their pH-value, bicarbonate concentration and CO_2 partial pressure corresponds to the physiological blood plasma values. Thus, based on this teaching one having ordinary skill in the art at the time the invention was made would have been motivated to adjust the bicarbonate and weak acid concentrations of Schambye, Veech I and Veech II in order to obtain a pCO2, which corresponds to the physiological blood plasma values.

The Appellants argue that Zander teaches away from the claimed invention because the specific composition in Zander as disclosed in column 2 is without a weak acid component. The Examiner disagrees. In column 2, beginning at line 35, Zander

discloses the ideal pH-value, bicarbonate concentration and pCO_2 for the solutions. Then beginning at line 58 Zander teaches that in addition the aqueous solutions should contain the desired electrolytes and that metabolizable anions of organic acids are desired for the therapy of acidosis (see lines 58-65). These acids include the claimed weak acids (see column 3, lines 62-68).

The Appellants make reference to column 6 of Zander, which requires using a weak acid in the form of acetate that is too high and dangerous to use. The Examiner does not believe that Zander teaches away from the claimed invention because Zander teaches that the weak acid concentration can vary (see column 4, lines 1-6 and column 4, line 53 to column 6, line 27).

The Appellants argue that the Patent Office has applied hindsight reasoning to justify the obviousness rejections. The Examiner disagrees. The CCPA has said that it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from the applicants' disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). In the instant case, all elements of the claimed invention are either inherently or explicitly disclosed by the cited prior art references. There is no element or part of Applicants' claimed invention, which is not either suggested or specifically or inherently taught by the cited prior art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Rosalynd Keys
Primary Examiner
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Rosalynd Keys
November 14, 2003

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